REMARKS

Claim 1 has been amended to permit the temperature-sensitive polymer to contain up to (but not including) 50 mole% of various comonomers that are not hydrophobically modified. Thus, it is clarified that the polymer must have at least 50% of the hydrophobically modified polyhydroxyalkyl(meth)acrylamide. This is supported on page 22 of the specification at lines 18-25. In addition, dependent claims 17-25 have been added that reflect preferred embodiments that were deleted from claims 2, 8, 9, 12, 14 and 15 in accordance with U.S. practice. (New claim 24 is former claim 9, which had been canceled.)

No new matter has been added and entry of the amendment is respectfully requested.

The Rejections Under 35 U.S.C. § 102

Claims 1-7 and 10-16 were rejected as assertedly anticipated by WO01/09198 (WO '198). This rejection is addressed by amendment. As set forth in claim 1, the polymer must be at least 50 mole% of hydrophobically modified hydroxyalkyl(meth)acrylamides and must have the property of having a lower critical solution temperature that changes during incubation in aqueous solution or medium. As shown in Table 3 of WO '198, polymers with 50% or more of the hydrophobically modified hydroxyalkyl(meth)acrylamide do not dissolve in water.

Applicants understand that Table 3 of WO '198 is confusing in that the column labeled "Comonomer ratio (mol/mol)" is actually inaccurate. As noted in Example 8, the copolymers in Table 3 are those prepared in Example 7. Turning to Example 7, on page 18 at lines 13-16, the actual mole ratios in Table 3 are listed. Thus, in Table 3, the mol/mol should read: 100/0; 95/5; 90/10; 80/20; 65/35; and 50/50 which matches the description of the polymers prepared in Example 7.

Since a polymer that contains even 50% of the hydrophobically modified hydroxyalkyl(meth)acrylamide does not even dissolve in water, it cannot have the feature required by the claim of having a lower critical solution temperature that changes during incubation in an aqueous solution or medium. Accordingly, the claim as now proposed is not anticipated by WO '198.

Claims 1-7 and 10 were rejected as assertedly anticipated by Cadée, *et al.* (*Polymer* (1999) 40:6877-6881). The Office asserts that Cadée discloses N-(2-hydroxypropyl)methylacrylamide dilactate coupled to dextran and formed into a hydrogel, citing page 6879, section 2.6. Respectfully, the disclosure of Cadée appears to have been misread. The polymer is that of a HEMA(lactate) which is 2-hydroxyethylmethacrylate (HEMA) dilactate. The structure of this is different from polyacrylamides as shown in the attached Exhibit 1. Thus, Cadée does not anticipate.

Claims 1-8 and 10 were rejected as assertedly anticipated by van Dijk-Wolthuis. This document does not anticipate for the same reason. Although the Office asserts that van Dijk-Wolthuis discloses N-(2-hydroxypropyl)methacrylamide olig(lactates) coupled to dextran, citing the "Experimental" section, in reality, this document only discloses the HEMA-lactate, which is a polyacrylate, not a polyacrylamide as shown in Exhibit 1. Thus, van Dijk-Wolthuis does not anticipate.

The Rejections Under 35 U.S.C. § 103

Claims 1-7, 10-13 and 15 were rejected as assertedly obvious over Neradovic, *et al.* (*Macromolecules* (2001) 34:7589-7591).

The Office acknowledges that Neradovic does not specifically disclose the micelles that were prepared in conjunction with a drug, thus justifying including claim 15 in the rejection.

However, this depends on assuming that the polymers in Neradovic are the same as those set forth in the claims. This is not the case with regard to amended claim 1 (and thus its dependent claims) in that the NIPAAm/ N-(2-hydroxypropyl)methacrylamide lactate copolymer is always at least 50% NIPAAm as shown in Table 1 of Neradovic. Thus, since the claimed polymers cannot contain even 50% of such a comonomer, Neradovic teaches away from the compositions as now claimed.

Claims 1-7 and 10-16 were rejected as assertedly obvious over Neradovic in view of U.S. 5,939,453. The '453 patent is cited in view of the recognition that Neradovic fails to teach an ABA block copolymer as well as adding a homing device, thus justifying including claims 14 and 16 in the rejection.

Again, the validity of the rejection depends on the assertion that Neradovic otherwise teaches the claimed polymer. It does not for the reasons stated above. Accordingly, this basis for rejection may also be withdrawn.

Conclusion

The amendment to claim 1 clarifies that the content of comonomers cannot be as much as 50% on a molar basis with respect to the hydroxyalkyl(meth)acrylamide that is hydrophobically modified. WO '198 does not anticipate because all of the polymers disclosed contain 50% or more of comonomer and even at 50%, the polymer cannot be dissolved in aqueous medium, and thus cannot meet the functional limitation of claim 1. Neither Cadée nor van Dijk-Wolthuis anticipates because they disclose polyacrylates, not polyacrylamides. Neradovic does not render the claims obvious either alone or in combination with the '453 patent because, again, all of the polymers disclosed in Neradovic contain at least 50% comonomers or more. Accordingly, applicants believe claims 1-8 and 10-16 are in a position for allowance and passage of these claims to issue is

respectfully requested. Applicants note that claim 8 has been rejected only over van Dijk-Wolthuis and this rejection is clearly in error as set forth above.

Should minor issues remain that could be resolved over the phone, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 313632002700.

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Respectfully submitted,

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